# ALL INDIA INSTITUTE OF MEDICAL SCIENCES ANSARI NAGAR, NEW DELHI-29. STORES SECTION (DO)

Ref. No. 09/Stores(DO)/Pead.Surg./PAC/2019-20/FSC Dated-20/09/2019

Sub:- Purchase of "Neonatal Safety Remote Monitoring and notification System – 01 Unit." for the Department of Pediatric Surgery at AIIMS, New Delhi-110029, on proprietary basis Inviting comments thereon.

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The Institute is in the process to purchase "Neonatal Safety Remote Monitoring and notification System – 01 Unit. at AIIMS, New Delhi from M/s. Masimo Corporation', USA through M/s. Gaur Surgicals, New Delhi The PAC Certifications by M/s. Masimo Corporation, USA as well as the user department are attached.

The above documents are being uploaded for open information to submit objections, comments, if any, from any manufacturer regarding proprietary nature of the equipment/item within 15 day from the date of issue/uploading the notification giving reference No. 09/Stores(DO)/Pead.Surg/PAC/2019-20/FSC. The comments should received in office of Stores Officer (FSC), Store Section (DO), Animal House Building, Near Biotechnology Building at AIIMS on or before 10/10/2019 upto 12.30 p.m. failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

Yours faithfully,

SR. STORES OFFICER (DO)

Encl: Related documents enclosed.

## Neonatal Patient Safety Remote Monitoring and Notification System for Neonatal ICU - 01 Unit

#### **Technical Specifications**

- 1. The system should provide Remote monitoring of patients in High dependency unit/wards and provide notification in case of any change in condition of patient.
- 2. The system should monitor the patients by the bedside and relay the data to a central monitoring station from where the patients can be monitored.
- 3. The notification system should be capable of sending alarm notifications to care givers and should have auto escalation features for providing fool proof redundancies.
- 4. Auto escalation should be programmable as per the care area need
- 5. It should be suitable for all types of patients: Pediatric, Infant, and Neonate
- 6. Patient monitor should provide continuous, simultaneous measurements and displays of the 4) Pleth variability Index parameter: 1)SpO2 2 )Pulse rate 3) Perfusion Index
- Should have the facility to measure these parameters for spot check and at fixed time intervals 7.
- Should be able to measure SpO2, Pulse Rate , Perfusion Index, Continuous Noninvasive 8. Hemoglobin ,Pleth variability through same single finger probe
- Beside monitor Should have selectable SpO2 averaging Modes- 2, 4, 8, 10, 12, 14 or 16 seconds & 9. Sensitivity -APOD, Normal and Max
- 10. Central Monitoring Station should be color touch screen at least 21" size
- Central station should have choice for selecting multiple domains and monitor up to 40 patients 11. at a glance in one single screen
- Central monitoring display should have Choice of icon and/or Numeric views, to quickly 12. investigate patient alarms
- Should have facility of comprehensive Review of trend data with Window selection of 10 minutes 13. to 96 hours display on the central monitoring station
- Should have Alarm notification system with multiple options including proprietary paging system 14. and enterprise paging system

System should be complete with paging transmitter and pagers (at least 10 nos ) with provisions for auto escalation

System Should allow 3rd party messaging with gateways that comply to TAP 1.6/1.8 over Ethernet or HL7

Individual Patient monitor should have rotational color touch screen with automatic, change to 17. horizontal or vertical view

र्एम्, बाजपेई / Dr. M. BAJPAI आचार्य एवं विभागाध्यक्ष / Professor & Head शिशु शल्य विभाग / Deptt. of Flediatric Surgery अ.भा.आ.सं., नई दिल्ली / A.I.I.M.B., New Dent : 170029

Devendra K. Yadav 15. Assistant Professor

Deptt. of Pediatric Surgery

A.I.I.M.S., New Delhi 26.

अभिता सेम Dr. AMITA SEN व्यक्तिक स्थातिक व्यक्ति व्यक्ति व्यक्ति **डॉ. संदि**य अग्रवाला /Dr.

विभाग / Department of Pediatric Surgery: दिल्ली/A.I.I.M.S., New Delhi-110029

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arjung Hospital, New Delhi Deptt. of Pediatric Surgery L.H.M.C. & K 3.C. Hospital New Delhi-11000



- Patient monitor should have facility to customize display to see parameter, waveforms or trend 18. patient monitor should have function with facility to select one or two parameters and move , expand or collapse parameter trend for real time analysis
- Individual monitor should have inbuilt battery backup of at least four hours 19.
- Display & measurement range, resolution and accuracy of beside monitor should be as follows 20.
  - Display and Measurement Range (infant/Neonate/Paed)
    - Plath Variability Index -0-100% a)
    - Oxygen Saturation (SpO2)- 0 100% **b**)
    - Pulse Rate (PR)- 25-240bpm
    - Perfusion Index (PI) -0.02.20% d)
  - Resolution (Neonate /infant /paed)
    - Oxygen Saturation (SpO2)-0-100% a)
    - Pulse Rate (PR) 1 bpm b)
  - Measurement range and Accuracy ( Neonate /infant /paed)
    - Saturation Range: 70% to 100% a)
    - Accuracy in no Motion -2% Accuracy in Motion—3% Accuracy in Low Perfusion-2% b)
    - Pulse Rate Range :25 -240 bpm
  - Accuracy in no motion -3 bpm accuracy in motion -5 bpm , Accuracy in Low Perfusion -3bpm
- The system should be US FDA and CE approved product
- The manufacture should have ISO certification for quality standards. 22.
- Should comply with following standards 23.
  - Safety Standards : ANSI/AAMI ES 60601 -1 , CAN/CSA C22.2 No 60601 -1 IEC/EN 60601 -1 a)
  - Pulse Oximeter Standards: ISO 80601-2-61 b)
  - Alarm Standards: IEC 60601 -1-8 Class B
  - EMC Standards: EN60601 -1-1-2, Class B d)
  - Degree of Protection : Type BF, Defib Proof

The system should have the capability of connectivity/ Integration with hospital hl7 Admit, discharge and transfer (ADT) system for patient data management. Should also have provision for bedside patient association via ADT.

- ssistant Professor pit. of Pediatric Surgery M.S., New Delhi-29 Should have option for integration into electronic medical record system using HL7 for automated documentation of patient data.
  - The system should support both wired and wireless installation. 26.
  - The vendor should quote price for sensors valid for at least Five years.

जिपई/Dr. M. BAJPAI आचार्य एवं विभागाध्यक्ष / Professor & Head शिशु शल्य विभाग / Depit. of Pediatric Surgery अभा आ सं , नई विस्ती / A.H.M.S., New Delly 110029

ला/Dr.(\$andeer Professor न्छत्रज्ञा अस्पताल, गई दिल्ली-29 orlung Hospital, New Delhi-29

Director Professor Deptt. of Pediatric Surgery C. Hospital: 

PSIMINNAMED



May 31, 2018

#### TO WHOM IT MAY CONCERN

This is to certify that the following technologies, and parameters are unique to pulse-oximeters and Co-oximeters manufactured by Masimo Corporation, are protected by patents, trademarks and or trade secrets as appropriate, and are proprietary to Masimo Corporation:

- 1. Signal Extraction Technology<sup>TM</sup> (SET<sup>TM</sup>): Proprietary technology protected by patents, trademark, and trade secrets, that allow the measurement of oxygen saturation in the blood, in spite of motion (Otherwise know as 'read through motion') and low perfusion up to 0.02 Perfusion Index (PI)
- 2. Rainbow SETTM or Rainbow Technology: Proprietary technology protected by patents, trademark, and trade secrets, that allow the non-invasive and continuous measurement of the following parameters:
  - i. Hemoglobin (SpHb)
  - Carboxyhaemoglobin (SpCO) ii.
- iii. Methaemoglobin (SpMet)
- Pleth Variability Index (PVI) iv.
- Acoustic Respiration Rate (RRa) ٧.

The combination of these measurements in one device is unique to Masimo, and is available as required in Masimo's Radical & Pulse Oximeter, Rad9, Rad97, and Rad 97 with NIBP

Further, to the best of our knowledge, no other company or manufacturer in the market, other than those who have licensed the technology from Masimo, produces, or can offer SETTM, Rainbow SET<sup>TM</sup>, Read through Motion, or Read through Low Perfusion up to 0.02 Perfusion Index, technologies and capabilities.

For and on Behalf of Masimo Corporation:

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Deptt. of resiliatric Surgery Hospital L.H.M.C. & K.S. Now Dading

**डॉ. एम.** बाजपेई / Dr. M. BAJPAI आचार्य एवं विभागाध्यक्ष / Professor & Head शिशु शल्य विभाग / Deptt. of Pediatric Surgery अ.भा.आ.चं., नई दिल्ली/A.I.I.M.S., New Delhi-110029

डॉ. देयेन्द्र कुमार यादय/Dr. Devendra K. Yadav सहायक आचार्य/Assistant Professor शिलु शत्य विभाग/Department of Pediatric Surgery अ.सा.आ.सं., नई दिल्ली/A.IJ.M.S., New Delhi-110029 Surdep Gawoh

हाँ संदिप आयाजा / Dr. Sandeep Agarwala St. संदिप आर्थापा / Dr. Sandeep Agarwala (th.) अधिता रोजा (Prof.) Amita Sen पद्मा अर्थापा / Dr. Sandeep Agarwala का आर्था कि मार्था (Prof.) Amita Sen पद्मा अर्था विभाग / Dr. Sandeep Agarwala का आर्था का मार्थ (Prof.) Amita Sen पद्मा अर्थ विभाग / Dr. Sandeep Agarwala का अर्थ (Prof.) Amita Sen पद्मा अर्थ विभाग / Dr. Sandeep Agarwala का अर्थ (Prof.) Amita Sen पद्मा अर्थ विभाग / Dr. Sandeep Agarwala (Prof.) Amita Sen पद्मा अर्थ (Prof.) Amita Sen (Prof.) Amita Sen पद्मा अर्थ (Prof.) Amita Sen (

अ.भा.आ.सं., नई दिल्ली/A.I.I.M.S., New Delhi-110029

# ALL INDIA INSTITUTE OF MEDICAL SCIENCES ANSARI NAGAR, NEW DELHI - 110 029

## Proprietary Article Certificate (PAC) (Machinery & Equipment)

1. The indented goods are Manufactured by M/s

Masimo, USA

2. Item Name

Neonatal Safety remote monitoring and

**Notification System** 

3. Model No.

Patient Safety Remote Monitoring and

**Notification System** 

4. Vital Technical Performance Parameters Required which makes the requirement Proprietary##

Rainbow Technology allows non invasive continuous measurement of SpHb, SpCO,

SpNet&PVI through one device

5. No other make or model is acceptable for The following reasons

Only Single Manufacturer

It is certified that market survey has been done and found that no other manufacturer is manufacturing similar/equipment specifications which can fulfill the vital requirements of end user.

डॉ. देवेन्द्र कुमार यादव/Dr. Devendra K. Yadav सहायक आचार्य/Assistant Professor रायु शत्य विभाग/Department of Padage James अ.भा.आ.सं., नई दिल्ली/A.IJ.M.S., New Deim-110029

द्धां. एम. बाजपेई / Dr. M. BAJPAI आचार्य एवं विभागाध्यक्ष / Professor & Head शिशु शल्य विभाग / Deptt. of Pediatric Surgery अ.भा.आ.सं., नई दिल्ली / A.I.I.M.S., New Delhi-110029

with Name, Designation, Department

डॉ. विशेष जैन/Dr. Vishesh Jain

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Date -09-02-2019

#### SECTION - XII MANUFACTURER'S AUTHORISATION FORM

The Director All India Institute of Medical Sciences Ansari Nagar, New Delhi-110029, India.

Dear Sir.

Ref: Your TE document No for Combined Patient SafetyNet™Remote Monitoring and Notification System- 15 Beds for Pediatric Surgery Department.

We, Masimo who are proven and reputable manufacturers Of Patient SafetyNet™Remote Monitoring and Notification System- 15 Beds. Having factories at USA, hereby authorize Gaur Surgicals having Reg. Office at 187, W.No. 3, Meherauli, New Delhi - 110030 to submit a bid, process the same further and enter into a contract with you against your requirement as contained in the above referred TE documents for the above goods manufactured by us.

We also state that we are not participating directly in this bid for the following reason(s): Company has decided to quote the Tender through their Authorized dealer.

We further confirm that no supplier or firm or individual other than Messrs. Gaur Surgicals Having address at -W.No. 3, Meherauli, New Delhi – 110030 is authorized to submit a bid, process the same further and enter into a contract with you against your requirement as contained in the above referred TE documents for the above goods manufactured by us. We also hereby extend our full warranty, CAMC as applicable as per clause 15 of the General Conditions of Contract, read with modification, if any, in the Special Conditions of Contract for the goods and services offered for supply by the above firm against this TE document.

We also hereby confirm that we would be responsible for the satisfactory execution of contract placed on the authorized agent and the spares for the equipment shall be available for at least 10 years from the date of supply of equipment.

We also confirm that the price quoted by our agent shall not exceed the price which we would have quoted directly"

Yours faithfully,

For Masimo Medical Technologies India Pvt Ltd.,

र्रुम. बाजपेई / Dr. M. BAJPAI आचार्य एवं विभागाध्यक्ष / Professor & Head शिशु शल्य विभाग / Deptt. of Pediatric Surgery अ.भा.आ.पा. नई दिल्ली / A.I.I.M.S., New Delhi-110029

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अग्रवाला /Dr. Sandeep Agarwala

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शस्य विभाग/Department of Particle